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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/781,504 | 05/06/2004 | Rafail Zubok | 532-3X4 | 2919 |
| 27538 | 7590 | 11/03/2006 | EXAMINER | |
| KAPLAN GILMAN GIBSON & DERNIER L.L.P. 900 ROUTE 9 NORTH WOODBRIDGE, NJ 07095 | | | SCHILLINGER, ANN M | |
| | | ART UNIT | | PAPER NUMBER |
| | | 3738 | | |

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/781,504 | ZUBOK ET AL. |
| | Examiner Ann Schillinger | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 February 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 25 June 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/15/04, 1/18/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 13-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramirez Jimenez (U.S. Pat. No. 5,458,641). Ramirez Jimenez discloses the following of claim 1: an insertion plate, comprising: a base (33a, 16a, 38); a first mounting element (18a) of the base operable to engage a first member of an intervertebral disc replacement device; and a second mounting element (34a) of the base operable to engage a second member of the intervertebral disc replacement device, wherein the first and second mounting elements cooperate to engage and orient the first and second members of the intervertebral disc replacement device for simultaneous insertion into an intervertebral disc space of a spinal column (col. 2, lines 37-41) (Figures 1, 3).

Ramirez Jimenez discloses the following of claim 2: the insertion plate of claim 1, wherein: each of the first and second members include articulation surfaces (60, 62) that cooperate to facilitate articulation of adjacent vertebral bones of the intervertebral disc space when the intervertebral disc replacement device is disposed in the intervertebral disc space (col. 5, 53-56); and the insertion plate cooperates to orient the articulation surfaces in substantial registration (shown in Figure 3) with one another for simultaneous insertion into the intervertebral disc space.

Ramirez Jimenez discloses the following of claim 3: the insertion plate of claim 1, wherein at least one of the first and second mounting elements includes a flange (22a, 44a) having a mounting hole (30a) therethrough, the mounting hole for receiving a fastener (32a, 40) to couple the flange to at least one of the first and second members of the intervertebral disc replacement device (col. 5, lines 12-14, 24-27, describes how element 40 couple the two flanges together).

Ramirez Jimenez discloses the following of claim 4: the insertion plate of claim 3, wherein the fastener is a mounting screw (32a) operable to engage a threaded bore in the at least one of the first and second members of the intervertebral disc replacement device.

Ramirez Jimenez discloses the following of claim 13: the insertion plate of claim 1, wherein the base is operable to detachably engage a flange of the first member of the intervertebral disc replacement device, and to detachably engage a flange of the second member of the intervertebral disc replacement device (element 16a can be separated from 18a and 34a as shown in Figure 3), wherein the first and second flanges include one or more respective through holes (24, 44, 44a) for receiving bone screws (26, 46, 26a, 46a) for fastening the first and second members to respective adjacent vertebral bones of the intervertebral disc space of the spinal column, and the base cooperates to orient the through holes of the first and second flanges of the intervertebral disc replacement device to have a configuration substantially similar to that of a spinal fusion plate when viewed from an anterior vantage point (col. 5, lines 20-24).

Ramirez Jimenez discloses the following of claim 14: the insertion plate of claim 13, wherein the base cooperates to maintain the first and second members of the intervertebral disc

replacement device in a substantially registered orientation for simultaneous insertion into the intervertebral disc space (col. 2, lines 37-41).

Ramirez Jimenez discloses the following of claim 15: an apparatus for replacing at least a portion of an intervertebral disc in a spinal column, comprising: first (18a) and second (34a) members of an intervertebral disc replacement device; and an insertion plate (16a) detachably coupled to each of the first and second members of the intervertebral disc replacement device (shown in Figure 3) and operable to orient them for simultaneous insertion into an intervertebral disc space of the spinal column defined by respective endplates of adjacent vertebral bones (col. 4, lines 34-41; col. 5, lines 11-20).

Ramirez Jimenez discloses the following of claim 17: a method for replacing at least a portion of an intervertebral disc in a spinal column, comprising the steps of: removing the portion of the intervertebral disc from the spinal column (col. 2, lines 30-32); and simultaneously inserting first (18a) and second (34a) members of an intervertebral disc replacement device into an intervertebral disc space of the spinal column (shown in Figure 4), the first and second members being engageable with and operable to permit adjacent vertebral bones defining the intervertebral disc space to articulate with respect to one another (col. 2, lines 52-62), and the first and second members being detachably (shown in Figure 3) coupled to an insertion plate (16a) that is operable to orient the first and second members with respect to one another for such insertion (col. 4, lines 34-41; col. 5, lines 11-20).

Ramirez Jimenez discloses the following of claim 17: the method of claim 17, further comprising the step of manipulating the first and second members as a single unit by way of the

insertion plate such that they may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (col. 4, lines 34-41; col. 5, lines 11-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez Jimenez in view of Keller (U.S. Pat. No. 4,997,432). Ramirez Jimenez discloses that the reference's implant can be inserted through conventional methods, but specifically using the insertion member and ledge claimed by the Applicant in claims 5-12 and 19. Keller teaches inserting a spinal disc plate using such a device and method. Keller teaches the following regarding claim 5: the insertion plate of claim 1, further comprising a ledge member (30,31) extending from a posteriorly directed surface of the base, the ledge member being sized and shaped to extend at least partially between the first and second members of the intervertebral disc replacement device such that they may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (col. 1, lines 32-46) (Figure 8).

Keller teaches the following regarding claim 6: the insertion plate of claim 5, wherein at least one of: at least one of the first and second spaced apart surfaces of the ledge member are contoured for engagement with respective surfaces of the first and second members of the

intervertebral disc replacement device (shown in Figure 8); and the first surface of the ledge member is curved (31) and the second surface of the ledge member is flat (30).

Keller teaches the following regarding claim 7: the insertion plate of claim 5, wherein at least one of: each of the first and second mounting elements includes a flange having a mounting hole therethrough, the mounting holes for receiving respective fasteners to couple the flanges to respective ones of the first and second members of the intervertebral disc replacement device; the mounting holes are oriented in a direction substantially parallel to a longitudinal axis of the spinal column (as disclosed above for the '641 reference); and the ledge member extends in a direction along the posteriorly directed surface of the base that is substantially transverse with respect to the longitudinal axis of the spinal column (Figure 8, reference '432).

Keller teaches the following regarding claim 8: the insertion plate of claim 1, further comprising an insertion member (the instrument shown in Figure 8) extending away from an anteriorly directed surface of the base and operable to facilitate movement of the intervertebral disc replacement device and insertion thereof into the intervertebral disc space (col. 5, line 58 thru col. 6, line 2).

Keller teaches the following regarding claim 9: the insertion plate of claim 8, wherein the insertion member includes an anteriorly extending stem (28, 29) to facilitate movement of the intervertebral disc replacement device such that the first and second members may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (col. 1, lines 32-46).

Keller teaches the following regarding claim 10: the insertion plate of claim 9, wherein the stem is sized and shaped for engagement with an insertion handle (24, 25) to further facilitate

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movement of the intervertebral disc replacement device (element 4 contains elements 7 and 8 for engaging the handle 24, 25 as described in col. 4, line 67 thru col. 5, line 2; col. 5, lines 54-57).

Keller teaches the following regarding claim 11: the insertion plate of claim 10, wherein the stem is detachable from the insertion handle to facilitate removal of the handle when the intervertebral disc replacement device is positioned within the intervertebral disc space (col. 5, lines 58-66).

Keller teaches the following regarding claim 12: the insertion plate of claim 11, wherein one of the stem and the insertion handle includes a bore (7) and the other of the stem and the insertion handle includes a tapered shaft (25, 25) that frictionally engages the bore to facilitate detachable engagement with one another.

Keller teaches the following regarding claim 19: the method of claim 17, further comprising the step of detaching the insertion plate from the first and second members (24, 25) after they have been coupled to the vertebral bones (col. 8, lines 33-35).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use this insertion device to properly place the implant in its necessary position.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez Jimenez in view of Sanderson (U.S. Pat. No. 4,105,407). Ramirez Jimenez does not disclose the implant as being in a sterile package. Sanderson teaches this in col. 2, lines 54-56. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to make the implant part of a sterile assembly package to prevent infection and safeguard the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
October 27, 2006

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER